Episode Transcript: The Uncertain Future of Plan C – A Hard Look Podcast

Opening Theme 0:08

Welcome to a Hard Look, the Administrative Law Review podcast from the Washington College of Law. We'll discuss how administrative law impacts your daily life. From regulatory actions by agencies and the litigation over them, to the balance of power among branches of the government. This is a Hard Look…

Alexander Naum 0:35

Hello there, I hope you're doing well and taking advantage of the warm weather by listening to this episode in a beautiful park covered in spring flowers. My name is Alexander Naum and I'm the Senior Technology Editor for the Administrative Law Review.

In June 2022, close to a year prior to this recording, the Supreme Court in *Dobbs v. Jackson County* made the shocking decision to overturn Roe v Wade and Planned Parenthood v. Casey. Among many reasons, this decision was shocking because these cases were firmly established in our society, with Casey being 30 years old and Roe being a year shy of half a century old at the time of the *Dobbs* decision. Generations of people across the nation relied on what was thought to be clearly established case law to access abortion procedures, while also relying on these cases as a shield to challenge state attempts to place an undue burden on abortion access.

All to disappear due to the opinions of six people serving on the highest court of the land.

Among the many issues with the Dobbs decision, include its broad rejection of substantive due process under the Fourteenth Amendment, which has been interpreted to protect the public from state action that intrudes on fundamental rights owed to people.

Potentially leading to more decisions that restrict other civil liberties, including the right to freely marry, the right to freely love, bodily autonomy, and so much more.

While this decision didn't ban abortion procedures completely in the U.S., it allowed states to restrict these procedures as they wish. Which at the time of this recording, has led to 13 states completely banning abortion, and 5 other states to substantially limit access to abortion procedures.

What's additionally frightening is the fact that the precedent created by Dobbs can be used to justify future decisions that broadly restrict access to abortion, even in states that recognize the medical necessity of this type of care.

In fact, The US District Court for the Northern District of Texas in *Alliance for Hippocratic Medicine v. FDA*, decided to overturn the FDA's approval of Mifepristone, also known as Plan C.

A drug along with other abortion drugs, that provides access for more than half of all abortions occurring in the U.S., according to the Kaiser Family Foundation.

The ruling gave the Federal Government seven days to appeal the decision before the ban would be in effect.

However, on the same day, The United States District Court for the Eastern District of Washington in the case Washington v. FDA, ruled that the FDA must keep medication abortion drugs available in states that have not restricted access.

Nevertheless, the Biden Administration appealed the Texas Court's ruling to the 5th Circuit Court of Appeals, which granted the administration partial relief, temporarily blocking the suspension of Mifepristone's approval; however, allowing other portions of the ruling which invalidated the FDA's conditions on the drug's use.

This is a fastly evolving issue, as of today, which we are recording on Friday, April 14th 2023, the Biden Administration and Danco Laboratories, the Manufacturer of Mifeprex, which is the brand name of Mifepristone has filed an emergency appeal with the Supreme Court to block the Texas's court's ruling.

And to keep this episode as up to date as possible for our listeners, I also wanted to provide you all with an update on the Supreme Court's ruling on the emergency appeal, which was made on April 21st, 2023. In the decision, the court decided to pause the Northern District of Texas's ruling, allowing access to Mifepristone to continue in states where its access is legal. However this isn't the end of this issue because they are also allowing the 5th Circuit to fully review the appeal. This means that it is extremely likely that this case will make it back to the Supreme Court, at a later time for a full review.

To help us in better understanding this issue, we are glad to be joined today with Lauren Saxe. Lauren is a 2L at American University Washington College of Law and is the Administrative Law Review's incoming Senior Symposia & Communications Editor. Lauren recently published a comment with the ALR Accord titled: "No Longer Viable: The Push For The FDA's Removal Of Mifepristone From The REMS Program Under Dobbs," which outlines the history of Mifepristone regulation by the FDA and recommends for the agency to remove the drug the overly restrictive REMS program.

(As a reminder to our listeners, theses are the personal opinions of Lauren Saxe and do not reflect the views of her employers, clients, organizations, or other individuals onto which these opinions can be imputed)

Lauren Saxe 5:21

Thanks for having me. Alex. I'm really happy to be here with you.

Alexander Naum 5:24

Yes, definitely. So let's start from the top. What exactly is Mifepristone? How is it used in patients and how does it differ from other abortion procedures?

Lauren Saxe 5:33

So, Mifepristone is one of two companion drugs, along with misoprostol, used to induce a medication abortion. Mifepristone is taken first, which blocks the body's receptors for the hormone necessary to sustain pregnancy. 24-48 hours after taking mifepristone, a patient takes misoprostol to induce uterine contractions which eventually result in terminating the pregnancy. During this process, patients usually experience heavy cramping and bleeding, similar to what one would experience during an early miscarriage. Unlike an in-clinic abortion, this can be done in the comfort of one's home and the actual medical process is different.

Alexander Naum 6:13

When was Mifepristone first developed and how did the international community respond to its initial development, as well as the U.S. at the time?

Lauren Saxe 6:26

Mifepristone was first developed in France by a man named Émile Baulieu around 1980. France was also the first country to approve it. It was first received there with extreme opposition, much of which came from religious and political extremist groups, but it was approved and the drug company who developed it eventually hopped on board despite threats. Internationally, more than a dozen countries approved the drug before the U.S., which had an especially hostile initial reaction to the drug. Baulieu, the creator of mifepristone, actually described its early introduction to the U.S. as "arriving like a splash of gasoline on a blazing fire."

Alexander Naum 7:06

Wow. Where did this initial opposition from Mifepristone stem from in the U.S.?

Lauren Saxe 7:12

Like other parts of the world, much of the early backlash in the U.S. came from extremist political and religious groups. However, mifepristone was also designated a banned substance and Presidents Reagan and H.W. Bush prohibited research into the drug. So there were multiple sources of opposition, coming not only from everyday citizens, but also our country's leaders, which in part led to mifepristone being approved in the U.S. much later than several other countries.

Alexander Naum 7:38

Wow. I mean, nevertheless, though mifepristone was approved in 2000. Can you talk more about the FDA's basis for this approval?

Lauren Saxe 7:46

The FDA approved mifepristone after a four-year review process. When it was approved, the FDA approved it with certain restrictions to assure safe use. And generally, when the FDA is approving any new drug, there is something within the agency called the Center for Drug Evaluation and Research, whose job is to evaluate new drugs before they can be sold. Physicians, statisticians, chemists, pharmacologists, and other scientists from the Center review a company's data about the drug, as well as its proposed labeling. If this review, which is independent and unbiased, establishes that a drug's health benefits outweigh its known risks, then the drug is approved for sale.

Alexander Naum 8:28

Going into like other parts of your comment, you significantly discussed the FDA's Risk Evaluation and Mitigation Strategy, also known as the REMS program. What exactly is this program and what does the Food, Drug, and Cosmetic Act say about the establishment of this program?

Lauren Saxe 8:45

The REMS program is reserved specifically for "certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks." It focuses on "preventing, monitoring, and/or managing a specific risk by informing, educating, and/or reinforcing actions to reduce the frequency and/or severity of its [potential effects]." This applies to a very limited number of medications (just over 60 currently) and although a REMS program is meant to reduce harm, the FDA specifies that it is not meant to reduce all adverse effects of a medication (although all foreseeable effects are mentioned in the prescribing information).

The Food, Drug, and Cosmetic Act is what establishes the FDA's REMS authority, and there is a division of the Act which recognizes that some drugs may require "elements to assure safe use," which are in a special category of REMS. These are drugs that have been "associated with serious adverse drug

experience." However, in the past, other drugs that have required ETASU have been released from the program.

Alexander Naum 10:04

What were those drugs that that were released from the program? Can you dive more into that?

Lauren Saxe 10:08

Yeah, so one of the examples I bring up in my comment is Tikosyn, an antiarrhythmic drug used to restore normal heart rhythm and maintain a regular, steady heartbeat. After determining that ETASU were no longer necessary for Tikosyn and that solely maintaining the Medication Guide as part of the drug's approved labeling was adequate, the FDA released it from the REMS program.

Alexander Naum 10:34

And just going back into Mifepristone. Where does it fit into this framework? Why was the drug initially added to this program?

Lauren Saxe 10:41

The FDA'S determination as to whether a REMS is necessary for a particular drug is a drug-specific evaluation. Its goal for the Mifepristone REMS is to mitigate the risk of serious complications that have been associated with mifepristone, requiring three different things: 1) prescribers have the necessary qualifications to assess whether the drug is appropriate for patients 2) ensuring that mifepristone is only dispensed by certain pharmacies or under the supervision of certified prescribers and 3) patients have been informed of the risks of the treatment regimen.

Particularly when a new drug is approved, it makes sense to be diligent and careful in who prescribes medications and how those medications are distributed. However, the FDA also implemented a process to modify or remove a REMS program, once it proves to be no longer necessary. After being on the market for well over two decades, the FDA now has much more information and data to support Mifepristone's safety efficacy. More than half of all abortions are now carried out via medication, and it's proven to be just as, if not more, safe than many "everyday" medications.

Alexander Naum 11:57

How has the FDA's regulation of Mifepristone under the REM's program changed over time?

Lauren Saxe 12:03

One of the more recent changes in the REMS program for Mifepristone that was a step in the right direction was in December 2021, when the FDA removed the restriction that required patients to get mifepristone in person at a healthcare facility. Alternatively, the FDA allowed patients to obtain mifepristone through the mail after a virtual appointment. This was in large part due to the difficulty many people had in retrieving medications in person as a result of the Covid-19 pandemic. However, in just the last week, further restrictions have been placed on mifepristone by a federal appeals court, one of which is that it can no longer be provided by mail, but I know we'll get to that a little later.

Alexander Naum 12:43

We definitely will get to that a little bit later. But still continuing on your comment, How has access to Mifepristone been affected after the Supreme Court's Decision in Dobbs?

Lauren Saxe 12:54

Mifepristone has been at the forefront of many discussions post-*Dobbs*. For those states that have banned abortion, mifepristone has obviously also been restricted in those states. Following the *Dobbs* ruling, there have been many concerns over interstate telehealth and prescriptions, as well as the prohibition of patients crossing state lines to obtain an abortion.

Alexander Naum 13:16

How has the FDA and more broadly, the Biden Administration, responded to this increase in abortion bans and restrictions by different states?

Lauren Saxe 13:24

In July 2022, the Biden Administration announced that federal law will preempt state laws banning abortions when emergency care is needed. Additionally, Attorney General Merrick Garland issued a statement that they will work with other arms of the federal government to protect and preserve access to reproductive care.

We saw a lot of different leaders in government speaking out and taking action after the *Dobbs* ruling, and we're seeing it again with the most recent ruling out of Texas. I think we'll be seeing more court challenges against the FDA in the coming months.

Alexander Naum 13:58

Yeah, I can imagine. And who wins this battle of federal preemption and states' rights? Does the Constitution and relevant jurisprudence have an answer?

Lauren Saxe 14:08

So, the battle between federal preemption and states' rights has created a messy landscape for governments, doctors, and patients. As I mentioned earlier, last summer the Biden Administration announced that federal law will preempt state laws banning abortions when emergency care is needed. There are so many factors and issues that complicate this, like mail delivery of abortion pills (which again, in the last couple of days has once again been restricted). Basically, until more lawsuits arise to establish precedent, the lines between states and federal laws will remain ambiguous and a clear answer doesn't exist yet.

That being said, if, in light of recent events and potential future proceedings, these questions might soon be more clearly answered, for better or for worse.

Alexander Naum 14:53

I would love to touch on some of your comment's recommendations. What should the FDA do moving forward to better expand access to Mifepristone?

Lauren Saxe 15:01

First and foremost, the FDA could remove Mifepristone from the REMS program. It has the authority to do so, and as we talked about earlier, other drugs have been previously and successfully removed when it was determined that their benefits outweigh their risks. Mifepristone has been available to the public for almost 23 years now and has been safely used by millions of patients over the years.

However, this is currently in flux due to the recent decision out of the Fifth Circuit regarding Mifepristone, so we'll have to wait and see how the appeals and potential further proceedings unfold before clear recommendations can be made moving forward. I specifically wrote about mifepristone being removed from the REMS program, but there are some larger barriers that are going to need to be tackled first.

Alexander Naum 15:46

And looking at other examples across the globe, I know that in many country's access to oral contraceptives and medication abortion is extremely easy for patients; how can the U.S. learn from these examples?

Lauren Saxe 15:59

I think the fact that many other countries have such accepted, widespread use of oral contraceptives and medication abortions further speaks to their safety and common use. Beyond oral contraceptives and abortion care, I think we can also look to other countries for more comprehensive, effective approaches to

sex education and reproductive care on the whole. As I outlined in the beginning of my Comment, there were more than a dozen other countries that approved mifepristone before the U.S., and although other nations that approved it had some backlash, none seemed quite as reluctant as the U.S. The U.S. also has one of the highest maternal mortality rates among developed countries, so I definitely think we could be open to more international approaches.

Alexander Naum 16:39

I definitely agree. While we have definitely talked about this subject briefly, I would love if we dive deeper into the recent decisions made over the past week. While your comment doesn't specifically touch on these recent decisions regarding Mifpristone and the circuit split on this issue, when this issue is reviewed by the Supreme Court, how do you think the Court will rule?

Lauren Saxe 17:05

This is a tough one, and I don't think I have a solid answer for that right now. *Dobbs* was so gutting to reproductive rights and a huge rollback on nearly 50 years of precedent, but this case also factors in the FDA's drug approval process and authority. This opens the door to attempt to invalidate any FDA approval, and could also deeply disrupt the pharmaceutical industry. So I am really not sure, but I do think we're going to see a lot more challenges, not only on abortion-related issues, but other drug- and FDA-related issues in the future following these decisions.

Alexander Naum 17:40

And touching on the broader implications of the Supreme Court reaching a restrictive decision that completely bans access to Mifepristone in the U.S.? What does this mean for patients seeking access to abortion?

Lauren Saxe 17:52

As I mentioned before, beyond the scope of mifepristone, one of the additional concerns with this case is the larger implications it will have in terms of the FDA's authority to approve both new and existing drugs. This could give an incredible amount of deference to judges to decide the safety of and access to any drug. This could include many life-saving drugs and vaccines. It's getting into murky waters in terms of access to healthcare.

In regard to abortion specifically, this is going to make it much harder for many people to access abortion. For some patients, this could strip them of their only option for abortion access. Of course, patients can still access other forms of medication for abortions and miscarriage treatment, including Misoprostol which is normally used in combination with Mifepristone. However, Misoprostol alone has been shown to be less effective, with an 80% success rate according to studies conducted by the American Academy of Family Physicians, as compared to the 95-99% efficacy of the two drugs taken in combination, according to Planned Parenthood.

Alexander Naum 18:54

I mean, it's great that even in this worst case scenario, patients will still have access to some form of medication for abortion and miscarriage treatment. However, patients shouldn't be left with a less effective option. This fight against mifepristone definitely appears to be politically motivated rather than grounded in accepted science. For my final question, should courts have the power to reject widely accepted science?

Lauren Saxe 19:18

I think that any ruling against widely accepted science gets into extremely dangerous territory, due to the implications we've been discussing as to how this could affect healthcare and FDA approval in a broader context. The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of our country's drugs, medical devices, food, cosmetics, and so on, and we should carry their rules and guidance with great weight. I don't think that it should be this easy to override decades of well-established scientific evidence, whether that's mifepristone or any other FDA-approved drug or item.

Alexander Naum 19:52

Well I want to thank you Lauren for your substantial contributions to today's episode and helping us to better understand the very uncertain future surrounding access to this form of reproductive healthcare.

I'd also like to acknowledge that this episode will be my last episode with A Hard Look, as I am graduating a couple weeks from today and my successor, ALR's new Senior Technology Editor, Bennett Nuss will be taking over the show. This has been an incredible year and I'm grateful to have had the opportunity to produce so many amazing episodes. I'd like to give a special thanks to the guests we had this season, the American Bar Association's Administrative Law Section, everyone at the Administrative Law Review, and of course listeners like you for your support.

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